

**Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Hilton, The Ballrooms, 620 Perry Parkway, Gaithersburg, MD.

***Clinical Risk Management of HPA Axis Suppression in Children  
with Atopic Dermatitis being treated with Topical Corticosteroids***

Draft Agenda for October 29, 2003

8:00	<b>Call to Order, Introductions:</b>	Joan P. Chesney, M.D., Chair
	<b>Meeting Statement:</b>	Thomas H. Perez, R.Ph., M.P.H. Executive Secretary
	<b>Opening Comments:</b>	Dianne Murphy, M.D. Director, Office of Counter- terrorism and Pediatric Drug Development and Jonathan Wilkin, M.D. Director, Division of Dermatologic and Dental Drug Products
8:30	<b>Atopic Dermatitis: Its Clinical Course and Therapeutic Options</b>	Bindi Nikhar, M.D. Division of Dermatologic and Dental Drug Products
9:00	<b>Overview of HPA Axis Suppression</b>	Jean Temeck, M.D. Division of Pediatric Drug Development
9:40	<b>FDA Experience: Topical Corticosteroids and HPA Axis Suppression</b>	Denise Cook, M.D. Division of Dermatologic and Dental Drug Products
10:10	<b>Post Marketing Adverse Event Reports</b>	ODS Staff
10:20	<b>Q &amp; A of Speakers</b>	
10:35	<b>Break</b>	
10:50	<b>Discussion of Question 1</b>	
11:10	<b>Framework for Risk Assessment and Management</b>	Anne Trontell, M.D. Office of Drug Safety
11:30	<b>Q &amp; A of Speakers</b>	
11:45	<b>Lunch</b>	
12:45	<b>Open Public Hearing</b>	
1:45	<b>Discussion of Questions 2-4 and Wrap Up</b>	

3:30     **Break**

*Section 17, Best Pharmaceuticals for Children Act, Adverse Event Reporting*

3:45     **Adverse Event Reports per Section 17 of BPCA**                      Solomon Iyasu, M.D.  
Division of Pediatric  
Drug Development

4:30     **Open Public Hearing**

5:00     **Committee Discussion of Presentations**

5:30     **Adjourn**